JUN 2 2 2005

K051284

510(k) SUMMARY

Respirics Inc. MD Turbo™

Submitter's Name, Contact Person, Address, Telephone Number, and Date Prepared

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Date Prepared:
January 31, 2005

Name of Device and Name/Address of Sponsor
Respirics Inc. MD Turbo™

Gilbert S. Mott, Jr.
Chief Executive Officer
Respirics Inc.
6008 Triangle Drive, Suite 101
Raleigh, NC 27617

Common Name
Metered dose inhaler accessory

Classification Name
Accessory to a Nebulizer/Metered Dose Inhaler, Spacer, Actuator
Class II – 868.5630

Predicate Devices
1. Ferraris Medical Inc. – Pocket Spacer™ (K992038)
2. Medtrack Products, LLC. – Doser™ (K935955)
3. Aradigm Corporation – SmartMist™ (K960593)

Device Description
The Respirics Inc. MD Turbo™ is a prescription accessory device designed for use with specific pressurized metered dose inhalers (pMDI). The MD Turbo™ is comprised of a triggering mechanism and dose counter. In addition to its primary function of assisting with the delivery of medications from pMDIs, the secondary function monitors the quantity of medication remaining in the pMDI canister.

MD Turbo™ is designed to work with a number of different style pMDIs, without modification. The entire pMDI, i.e., canister and plastic actuator, is inserted into the MD Turbo™. If necessary, the pMDI can be removed for cleaning or if the MD Turbo™ becomes inoperable.

Once the pMDI has been placed into the MD Turbo™, the device is prepared for use by the depression of a loading lever. After the loading lever is depressed, the pMDI can be triggered to deliver the prescribed medication through either breath-actuation or manual actuation. For breath-actuation, the patient inhales through the pMDI actuator mouthpiece that has been inserted into the MD Turbo™. When the inspiratory flow of the patient reaches the target inspiratory flow rate, the device mechanism is triggered to actuate the pMDI canister and the medication is delivered to the patient. Alternatively, the patient can trigger MD Turbo™ to actuate the pMDI canister by depressing a recessed button on the back of the device.

The MD Turbo™ also functions as a dose counter. Once a pMDI has been inserted into MD Turbo™, the patient selects the number of doses contained in the pMDI canister. The number is displayed on an LCD on the side of the device. Every time the MD Turbo™ is activated, the counter decrements appropriately. When the counter reaches 20 or fewer doses, the number display will start to flash.

Intended Use

MD Turbo™ is intended to assist with the delivery of aerosolized medications when used in conjunction with commercialized pressurized metered dose inhalers (pMDI). MD Turbo™ is also intended for use by patients to count the number of doses remaining in their pMDI.

Technological Characteristics and Substantial Equivalence

The MD Turbo™ has no significant change in design, materials, energy source or other technological characteristics compared to the predicate devices. MD Turbo™ is similar in function to these predicate devices. MD Turbo™ combines features that have in the past only been available as separate commercialized devices. The MD Turbo™ is therefore compared to three predicate devices: the pMDI medication delivery function is compared to the Ferraris Medical Pocket Spacer™; the counter function is compared to the Meditrack Products Doser™; and the actuation mechanism is compared to the Aradigm Corporation SmartMist™ Asthma Management System.

As an accessory to pMDI medication delivery, MD Turbo™ differs from the predicate Pocket Spacer™ in that MD Turbo™ is an active mechanical device rather than a passive mechanical device. As an accessory to pMDI dose counting, both the MD Turbo™ and the predicate Doser™ use

electromechanical mechanisms. With regard to the breath-actuation mechanism, the MD Turbo™ uses a mechanical mechanism and the predicate SmartMist™ uses an electromechanical mechanism.

Performance Data

Respirics performed cascade impaction tests for particle size comparison, and an HPLC analysis for total dose output comparing MD Turbo™ with pMDI to the Pocket Spacer™ with pMDI and to pMDI alone.

1. Total dose output (HPLC): MD Turbo™ with MDI, Pocket Spacer™ with pMDI, and pMDI alone
2. Particle size distribution (Cascade Impaction): MD Turbo™ with pMDI, Pocket Spacer™ with pMDI, and pMDI alone

Conclusions

The MD Turbo™ has similar intended use and similar performance characteristics to the predicate devices. Furthermore, the results of the testing raise no new issues of safety and effectiveness. Therefore, the MD Turbo™ is substantially equivalent to the predicate devices.

Table 1. Biocompatibility of Materials in Contact with Patient or Air Flow Path / K051284

Part Name	Diagram#	Part#	Material	Patient Contact	Airway Continuity	Biocompatibility Test	Page Ref
Case Half, Side A	1	1	GE Lexan 144-112	Yes	No	Cytotoxicity Sensitization Irritation/Intracutaneous Bioburden	Appendix 3, pg 1-pg 5 Appendix 3, pg 6-pg 7 Appendix 3, pg 6-pg 7 Appendix 3, pg 8
Pushlink	1	5	GE Lexan 144-112	Yes	Yes	Cytotoxicity Sensitization Irritation/Intracutaneou Bioburden	Appendix 3, pg 1- pg 5 Appendix 3, pg 6-pg 7 Appendix 3, pg 6-pg 7 Appendix 3, pg 8
Vane	1	7	GE Lexan 144-112	Yes	Yes	Cytotoxicity Sensitization Irritation/Intracutaneous Bioburden	Appendix 3, pg 1- pg 5 Appendix 3, pg 6-pg 7 Appendix 3, pg 6-pg 7 Appendix 3, pg 8
Vane Lock	1	8	GE Lexan 144-112	Yes	Yes	Cytotoxicity Sensitization Irritation/Intracutaneous Bioburden	Appendix 3, pg 1-pg 5 Appendix 3, pg 6-pg 7 Appendix 3, pg 6-pg 7 Appendix 3, pg 8
Case Half, Side B	2	1	GE Lexan 144-122	Yes	No	Cytotoxicity Sensitization Irritation/Intracutaneous Bioburden	Appendix 3, pg 1-pg 5 Appendix 3, pg 6-pg 7 Appendix 3, pg 6-pg 7 Appendix 3, pg 8
Bezel, Counter	2	3	GE Lexan 144-112	Yes	No	Cytotoxicity Sensitization Irritation/Intracutaneous Bioburden	Appendix 3, pg 1-pg 5 Appendix 3, pg 6-pg 7 Appendix 3, pg 6-pg 7 Appendix 3, pg 8

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 22 2005

Respirics, Incorporated
C/O Mr. Edwards M. Basile
King & Spalding LLP
1700 Pennsylvania Avenue, N.W.
Washington, D.C. 20006-4706

Re: K051284
Trade/Device Name: MD Turbo
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: May 12, 2005
Received: May 13, 2005

Dear Mr. Basile:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051284

Device Name: MD Turbo

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MD Turbo is intended to assist with the delivery of aerosolized medications when used in conjunction with commercialized pressurized metered dose inhalers (pMDI). MD Turbo is also intended for use by patients to count the number of doses remaining in their pMDI.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K051284